

An Assessment of Cough Medicine Dispensing Practice to Children Under Two Years Old in Pharmacies in Ho Chi Minh City Using Simulated-Patient Method

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Info Article

Submitted: 30-09-2019

Revised: 20-02-2020

Accepted: 02-03-2020

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ABSTRACT

Over-the-counter (OTC) cough and cold medications (CCMs) have been used to treat the symptoms of upper respiratory infection in children for decades. The safety of CCMs in children has been questioned. The data on knowledge of pharmacists in supplying cough medicines for children under two years have been limited. This study aimed to evaluate the pharmacists' dispensing decisions to manage the cough in children under two years old. A descriptive cross-sectional was carried out in 300 pharmacies in 15 districts in Ho Chi Minh City, Vietnam. The pharmacists were interviewed by a simulated patient. The results showed that, information that pharmacists actively asked the client about the patient and disease symptoms was limited. Most pharmacists did not provide adequate instructions and counsel about using drugs for clients. Only 22/300 (7.33%) of pharmacists appropriately provided cough medicines for children under 2 years old. The main reason of inappropriateness was the deficiency of knowledge about updated contraindication of N-acetylcysteine (93.17%). Pharmacists in pharmacies located in districts 3, 11 and Binh Thanh had higher rate of rational provision than those in other districts. A good and full understanding of the patient symptom helped the pharmacists supply cough medicines more reasonably. The limited caution of pharmacists and the low proportion of pharmacists updating contraindication of N-acetylcysteine should be considered as a warning sign in pharmacy practice in Ho Chi Minh City, Vietnam.

Keywords: Cough medications, Children, Pharmacy.

INTRODUCTION

Nowadays, there is a tendency that patients usually self-treat their common symptoms by requesting for over-the-counter (OTC) medicines in pharmacies, the prevalence of self-treatment ranged from 0.1 to 100 percent among different countries (Dnyanesh Limaye *et al.*, 2017). Cough and cold medicines were one of the most widely self-treatment drugs (13.9%); and cough and cold symptom was the top health complaint in pharmacy (61.43%) (Dnyanesh Limaye *et al.*, 2017). According to the warnings of the United States Food and Drug Administration (FDA) and Health Professors, OTC cough and cold medications (CCMs) should not be used for infants and children under two years old and ought to be provided children aged over six with caution (Diane E Pappas, 2015; O'Grady, 2017; British National Formulary for Children, 2017). Besides, a

critical analysis of a Cochrane review indicated that the efficiency of OTC medicines was not strong enough in acute cough (De Blasio, 2011). The data on supplying of OTC CCMs for children under two years old in Vietnam have been limited. In Ho Chi Minh City, most of the pharmacies were inner-city ones. This study aimed to evaluate the pharmacists' dispensing decisions to manage the cough in children under two years old in inner-city pharmacies in Ho Chi Minh City, Vietnam.

MATERIAL AND METHODS

Study design and subjects

This study was a descriptive cross-sectional study using the simulated-patient (SP) method. We included inner-city pharmacies if they were on duty and located in Ho Chi Minh City, Vietnam, during the study period, from September to October, 2018. In case the pharmacists detected the SP's

simulation or did not answer the questions asked by SP, these visits would be excluded from further evaluation. The conversation between the SP and the pharmacists would be also for assessment if the SP did not follow the scenario or the audio recording was incomprehensible.

Sample

We conducted a pilot study in thirty pharmacies, of which two pharmacists from two pharmacies (accounted for 6.7%) had appropriate cough medicine dispensing decision (CMDD). The minimum sample size was calculated to be 267 assuming a prevalence rate of appropriate CMDD of 6.7% reported in our previous pilot study, with the allowable error of 3%. We recruited 300 pharmacies for survey to take refusals into account. From the list of all pharmacies in 15 inner-city districts in Ho Chi Minh City, we randomly selected twenty pharmacies per district by using random list generated by Microsoft Excel 2016.

Definitions

Cough medicine dispensing decision (CMDD) was defined as the decision of pharmacists on dispensing drugs for the patient. *Appropriateness of CMDD* was defined whether the pharmacist satisfied all of the following criteria: (1) the pharmacist did not provide patients with antibiotic; (2) the pharmacist provided suitable preparations for children under two years old and (3) the pharmacist updated the contraindication of N-acetylcysteine that was not used for children under two years old. Other cases of CMDD were considered as inappropriate.

Study process

There were four steps in this study: (1) Developing the scenario and training SPs: Three fourth-academic year students of Faculty of Pharmacy, University of Medicine and Pharmacy at Ho Chi Minh City, also the researchers, were the SPs. The scenario was designed by the researchers to survey information for further assessment. The SPs were trained before their visits to the pharmacies. Training took place in a lecture room on campus; (2) Evaluation of the unity of all SPs: After the end of the training, the SPs were evaluated. In the evaluation process, the SPs conducted the scenario in the Clinical Pharmacy Laboratory with a Doctor of Pharmacy acting as a pharmacist on duty. Then the audios recording these conversations were evaluated by the researchers specializing in the SP method so as to

ensure the quality and unity of SP's visits; (3) Trials for scenario accomplishment: Trials for scenario were carried out in ten pharmacies in advance to detect possible shortcomings of the scenario. No significant deficiencies in the constructed scenario were identified; (4) Conducting the research by SPs method: After completing the scenario, three researchers conducted the surveys on study population mentioned above.

The scenario

A 21-year-old teenager (SP/ client) visited a pharmacy asking for cough preparation. This initial SP's request would be the opening statement to initiate the SP-pharmacist interaction.

The patient was the assumed younger sister of SP. She was 14 months old and weighed approximately 10 kilograms. There was no drug allergy established before. The patient had a productive cough with clear and diluted sputum for around three days. Her cough got worse at night. Other symptoms were slight nasal congestion, runny nose, and loss of appetite. She did not take any medications. The pharmacist's first decision was noted.

After that, the client actively asked to be provided EXOMUC 200, containing N-acetylcysteine as an active ingredient. The reason for this request was because the SP had recently used this mucolytic to self-medicate his/her sputum cough, which made the SP believe that EXOMUC 200 would be effective for the same case of his/her younger sister. The pharmacist's perspectives, determination and counsel were recorded and evaluated.

Data collection

Based on specific questions about the patient's information of the pharmacist, the SP provided corresponding information for these by relying on the scenario's content. In case the pharmacist did not fully exploit the patient's necessary information, the SP must actively provide them to complete the survey and obtain the objectives of this study. We collected patients' data that pharmacists were interested in, including patients' general information, type of cough, accompanying symptoms, and cough characteristics. The data on CMDD and pharmacists' counsel were also obtained.

Data analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS) program, version 22.0.

Patient's information that pharmacists were interested in and dispensing decisions were presented as a percentage. The comparison of the rates of appropriate CMDDs among districts was assessed using the Chi-square test or Fisher exact test. The level of statistical significance was specified at $p < 0.05$.

RESULTS AND DISCUSSION

In total, 300 retail pharmacies in 15 inner-city districts in Ho Chi Minh City were included in this study. There were nine pharmacies (9/300, 3.0%) belonging to two specific pharmacy chains. The rest (291/300, 97.0%) were the independent pharmacies which were pharmacist-owned retails and not directly affiliated with any chain of pharmacies or publicly traded company. There were twenty pharmacies per district, which showed an equality of the numbers of pharmacies located in each district. Fifteen districts in this study included District 1, District 2, District 3, District 5, District 6, District 7, District 8, District 10, District 11, District 12, Binh Thanh District, Phu Nhuan District, Tan Binh District, Thu Duc District, and Go Vap District.

Patients' information that pharmacists were interested in

Most pharmacists interested in the age of patients (68.33%), type of cough identification (74.67%). However, other information about the patients were limited (Table I). There were several studies conducted to assess the approach practices of community pharmacies in the patient's data collection. Similar to our study, information on patient's age was also concentrated the most (90.3%) in the study conducted in Ethiopia in 2016, surveying the sale of medicines for diarrhea management for children (Abegaz *et al.*, 2016). The proportion of pharmacists who were interested in the patient's age in our study was lower than those involved in Hussain's study (83.3%) (Hussain *et al.*, 2012), and Golnaz V's study (98%) (Golnaz *et al.*, 2015). There were 23% of pharmacists asking for a patient's weight in Abegaz's study, which experienced a lower percentage than that in our study (Abegaz *et al.*, 2016). In terms of patient's medication and treatment history, the proportions of pharmacists concentrated on were higher than those in this study (at 23.9% and 36.3%, respectively) (Abegaz *et al.*, 2016). Generally, the participating pharmacists seldom proactively examined the information about the patient and the symptoms. The data about the patient had a

significant impact on the effectiveness of the medication since they were relevant to the incidental risk to the patient, such as drug allergy, undesirable drug reaction and adverse drug interaction. Thus, the lack of information about the patient could influence the appropriateness of the cough medicine dispensing decisions (CMDDs) that the pharmacists made afterward.

Pharmacists' dispensing practices Cough medicine dispensing decisions (CMDDs)

The most common CMDD was to dispense herbal cough syrup (61%) and antibiotics (43.44%). The pharmacists rarely provided drug information for the patients (Table II).

Children under six years of age often have a cold or flu, about eight times per year, especially from September to next April, with typical symptoms lasting in roughly 14 days (Diane E Pappas, 2015; Anne B Chang *et al.*, 2018). In this study, the data were collected from surveys in September and October of 2018, also the period of climate and weather change in Ho Chi Minh City, which might be a cause for the increased respiratory infections in children. The prediction of most of the pharmacists about patient's disease and condition which makes their concentrations about accompanying symptoms was reasonable.

The antibiotics usually supplied for the patient were cefixime and cephalexin. In addition, the decision to provide SPs with antibiotics accounted for nearly half of the pharmacies. In most of these cases, the pharmacists were interested in the patient's weight for proper dose adjustment. Nevertheless, it was inappropriate to provide children with antibiotics without a physician's prescription.

Abuse of antibiotics makes some type of multi-resistance. Furthermore, antibiotics abuse can lead to other problems such as intestinal bacteria dysfunction. The habit of using antibiotics of Vietnamese people is at an alarming level. The sale of antibiotics brings a big profit, leaving few immediate consequences while the efficiency is quite high, so it was the choice of most pharmacies in Vietnam. To regulate the use of antibiotics, a project to enforce the regulations of prescribing and dispensing prescription-only-medicines (POMs), especially antibiotics in three years from 2017 was approved by the Ministry of Health (Vietnam Ministry of Health, 2015). In addition to the intervention of health workers, the people's knowledge expansion will be an advantageous factor to help reduce antibiotic resistance.

Table I. Patients' information that pharmacists were interested in

Category	Subcategory	Frequency (n = 300)	Percentage (%)
Patients' general information	Age	205	68.33
	Weight	118	39.33
	Medical history	0	0.00
	Allergy history	1	0.33
	Current medications	5	1.67
Type of cough information	Type of cough identification	224	74.67
	Sputum color	11	3.67
	Sputum viscosity	11	3.67
Other accompanying symptoms	Runny nose	111	37.00
	Nasal congestion	69	23.00
	Fever	41	13.67
	Rash	1	0.33
	Loss of appetite	0	0.00
	Other	3	1.00
Cough characteristics	The time of initiation	40	13.33
	Frequency	33	11.00
	Being treated before	14	4.67
	Similar symptoms before	2	0.67

Table II. Pharmacists' dispensing decisions and counsel

Category	Subcategory	Frequency (n = 300)	Percentage (%)
CMDD	Herbal cough syrups	183	61.00
	Antibiotics	130	43.33
	Antihistamines and vitamins	68	22.67
	N-acetylcysteine derivatives	4	1.33
	Central antitussives	3	1.00
	Usage	114	38.00
	Dose	38	12.67
Pharmacists' counsel	Indications	2	0.67
	Contraindications	0	0.00
	Cautions, adverse drug reactions	0	0.00
	Patient should go to the doctor after this visit	3	1.00
	Patient should go to the doctor if the medication is not efficient	1	0.33

Another priority medicine selection was herbal cough syrup preparations, at 61% in total, which was recommended as the safest kind of preparation to reduce annoying cough children under two years old (Anne B Chang *et al.*, 2018; Shan Yin, 2018). Furthermore, honey (2.5-5 mL) can be given to children directly or diluted with tea or fruit juice. In the absence of honey, corn syrup can be used instead. Honey is moderately effective for children who cough nocturnally. It also does not harm children over one year old. However, parents should avoid using honey for children under one year of age because of the risk of similar symptoms

of botulism (Shan Yin *et al.*, 2018; Diane E Pappas, 2015).

Pharmacists today play an important role in community health care because they are close to the public and usually directly counsel people on drug administration. The result of this study demonstrated the limitation in the role of pharmacists in giving patient advice in Ho Chi Minh City. By contrast, in the study of Abegaz, the number of pharmacists that consulted dosage, frequency, indication, adverse drug reactions of drug were higher than those in our study (Abegaz *et al.*, 2016).

Table III. Reasons for inappropriate CMDDs (n = 278)

Reasons	Frequency (n = 278)	Percentage (%)
The pharmacist did not know about N-acetylcysteine contraindication	259	93.17
The pharmacist provided at least one antibiotic	130	46.76
The pharmacist provided a contraindicated drug	30	10.79

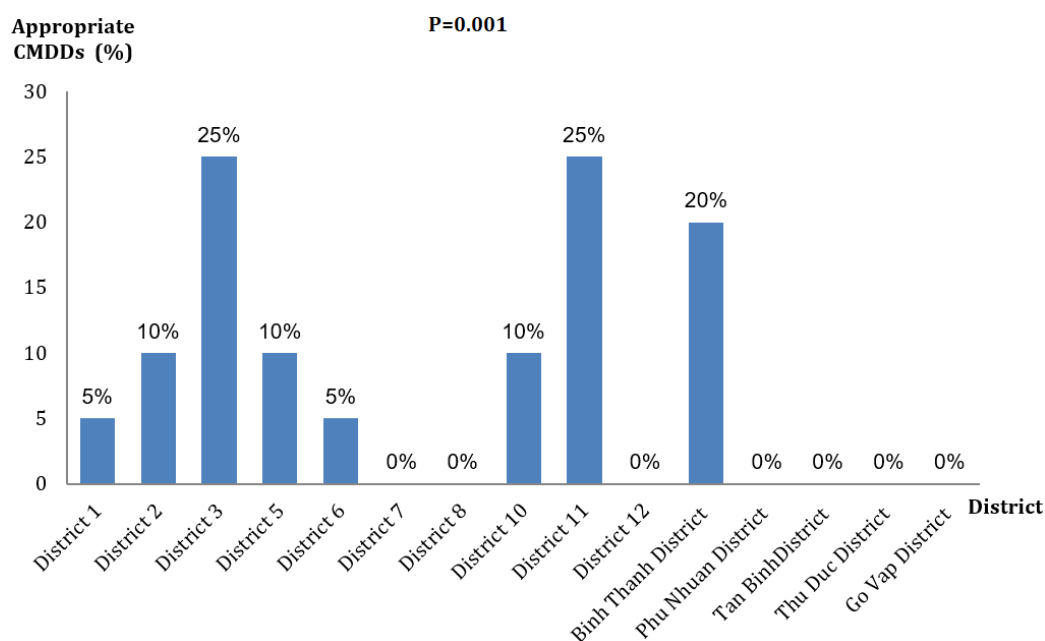


Figure 1. The rate of appropriate CMDDs

Table IV. Factors associated with the appropriate CMDDs

Information that pharmacists were interested in (n=300)	Appropriate, %	p value
Patient's general information	Yes: 8.21 No: 4.30	0.163
Type of cough information	Yes: 8.70 No: 3.23	0.191
Other accompanying symptoms	Yes: 7.73 No: 5.38	< 0.001
Cough characteristics	Yes: 10.75 No: 5.31	< 0.001
Giving SP* counsel	Yes: 1.45 No: 19.35	0.147

*SP: Simulated patient

In Horvat's study of the approach to guidance related to paracetamol for headache symptoms, the two information most often provided by the pharmacists were the dose and undesirable effects of the drug (Horvat, 2012). The object of a 14-month-old child in the study was the subject that needed to be particularly cautious in using drugs

because children had not only incomplete physiological functions but also unclear knowledge and perception of physical changes when using drugs. Therefore, pharmacists need to pay more attention to drug counseling. However, this study outcome showed that no pharmacists concentrated on drug caution.

Pharmacists' knowledge about contraindications of N-acetylcysteine

The proportion of pharmacists having updated contraindication of EXOMUC 200 (active ingredient: N-acetylcysteine) in this study was only 13.67% (41/300). There were three pharmacists (accounted for 1%) refusing to give information about their knowledge of this derivative's contraindication, so that they were regarded as "Data deficiency for conclusion".

Since 2015, N-acetylcysteine has been categorized as one of the medicines which is not indicated for children under two years old. According to Health Professors, N-acetylcysteine derivatives may not help reduce symptoms but make the cough in children more severe as symptomatic treatment may delay treatment of underlying conditions (US Food and Drug Administration, 2017; Shan Yin *et al.*, 2018; Diane E Pappas, 2015; O'Grady KAF *et al.*, 2017).

The rest (85%) had not updated that children aged under two years old were recommended not to be treated by N-acetylcysteine. The reason for this problem may be due to the lack of updated information on medical staff and drug sellers with the new guidelines for the treatment of cough in children. Currently, there are not plenty of drugs with similar effects, which makes the choice of the pharmacists relatively narrow. Experience is also a very dominant factor in the sale drugs determination of pharmacists, so N-acetylcysteine derivatives were usually the priority choice in this disease. Moreover, undesirable effects of N-acetylcysteine also occur with low frequency in children, so the pharmacists do not pay much attention to the N-acetylcysteine administration (Vietnam Ministry of Health, 2017; Mai Phuong Mai *et al.*, 2017). Therefore, there is a necessity for improvement in continuing education for pharmacy staff. By improving their understanding of contraindication of preparations containing N-acetylcysteine, the therapeutic use of these drugs may be refined.

The rate of appropriate CMDDs

There were 22 pharmacists from 22 pharmacies (accounted for 7.33%) had appropriate CMDDs. The main reason for inappropriate CMDDs was that pharmacist did not know about N-acetylcysteine contraindication (259/278, 93.17%). Other reasons for inappropriateness were shown in Table III.

In terms of antibiotic use for cough treatment in children, the proportions of inappropriateness in several previous studies were all higher than this study's outcome. Regarding the hospital practice, the inappropriate antibiotics prescriptions in Northern Tanzania accounted for 68.9% (Gwimile J.J. *et al.*, 2012), while the data for the study in Addis Ababa was 86.6% (Tekleab AM *et al.*, 2017). Meanwhile, in terms of the pharmacy practice, another study in Tanzania showed that up to 92.3% surveyed pharmacists dispensed antibiotics without prescription, in which antibiotics for cough treatment accounted for 75% inappropriate cases (Horumpende P.G. *et al.*, 2018). The lower proportion of the inappropriateness due to antibiotics provisions may be relevant to the various kinds of medicines that were surveyed in this study. While above studies only focused on antibiotics, this study determined the proportions of both antibiotics and other contraindicated drugs. Therefore, antibiotic use made up a lower proportion of inappropriate CMDDs in total.

Beside the lack of carefulness, a poor understanding of the ingredients in cough medicines was suggested as a cause of the inappropriate dispensing decisions (Kigen G. *et al.*, 2015). A study among hospitalized children across Kenyan hospital between 2002 and 2015 showed that educational, policy mass media interventions and an expansion of the pediatric workforce led to the overall decline in the inappropriate use of cough medicines (Mochuki M. *et al.*, 2016). Thus, the improvement in the knowledge of pharmacists is essential to reduce the proportion of the inappropriateness.

The rates of pharmacists having appropriate CMDDs were significantly different from participating districts in Ho Chi Minh City ($p = 0.0014$). There was a quarter of 20 participating pharmacists in District 11 who made rational medicines provision decisions, and so was the figure for District 3. These were the highest proportions of rational CMDDs among 15 districts in this research. On the contrary, neither of participating pharmacists in District 7, 8, 12 and Phu Nhuan, Go Vap, Thu Duc District satisfied criteria for an appropriate CMDD (Figure 1).

The rate of appropriate CMDDs in groups of pharmacists actively asking about patient's accompanying symptoms was higher than those of groups did not concern about data of accompanying symptoms (7.73% and 5.38%, respectively, $p < 0.001$). Pharmacists determining

the cough's characteristics made more appropriate CMDDs than those who did not verify the feature of cough symptoms (at 10.75% and 5.31%, respectively, $p < 0.001$) (Table IV). Explaining this issue, pharmacists, who had more information on cough's characteristics, and accompanying symptoms, would be more careful to decide dispensed drugs.

Nevertheless, the different outcomes were shown in a study on antibiotics dispensing practice in Tanzania. It displayed that the lack of instructions on how to take medicines and not explaining the adverse drug reactions to clients led to the poor quality of community practice (Horumpende PG *et al.*, 2018). These outcomes showed that the less information that the pharmacists actively asked the clients, the fewer appropriate dispensing decisions the pharmacists made. In general, patient-centered care should be promoted to help the pharmacists to interact more effectively with patient, which improves the understanding of the pharmacists about patients' status and the proportion of appropriateness (Horvat N. *et al.*, 2012).

This study was the first one in Vietnam that survey the cough medicine dispensing practice to children under two years old by simulated-patient method with a significant sample size of 300 inner-city pharmacies in Ho Chi Minh City. Despite these encouraging findings, our study had some limitations. First, the researchers could not survey the information on qualifications of the pharmacists, which may be a factor associated with the appropriate CMDDs. The reason was that this kind of information was not sufficient in all pharmacies. Secondly, the pharmacies included in this study were inner-city ones, that could differ from those in urban districts, so the results could be generalized only for inner-city pharmacists in Ho Chi Minh City. Therefore, a future larger study may be necessary to overcome this issue.

CONCLUSION

The rate of the appropriateness of CMDDs was low. A good and full understanding of the patient symptom helped the pharmacists supply cough medicines more appropriately. The limited caution of pharmacists and the low proportion of pharmacists updating contraindication of N-acetylcysteine should be considered as a warning sign in pharmacy practice in Ho Chi Minh City, Vietnam.

ACKNOWLEDGEMENT

The authors express a deep sense of gratitude toward Department of Clinical Pharmacy, Faculty of Pharmacy, University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam for helping us complete the scenario and guarantee the unity of researchers (also SPs) in the trials of this study process.

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